

Notice of Allowability	Application No.	Applicant(s)	
	10/500,302	RASMUSSEN ET AL.	
	Examiner	Art Unit	
	Satyanarayana R. Gudibande	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.
2. ☒ The allowed claim(s) is/are 1-9.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>6/28/04</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I invention (claims 1-9) in the reply filed on November 18, 2005 is acknowledged.

Claim 10 is being withdrawn from further consideration as being drawn to non-elected invention.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Edward Meilman on January 11, 2006.

In the instant application, applicants claim a process of purification of a nona- or a decapeptide using a dissolution solvent mixture consisting of polar solvents and precipitation solvent mixture consisting of polar and non-polar solvents.

The following is an examiner's statement of reasons for allowance: The closest prior art, Sakamoto, et al., Journal of Antibiotics, 1993, 46, 1788-1798, teaches the isolation and purification of cyclosporin A. However, the prior art does not teach or suggest, alone or in combination, the instantly claimed purification method for the nona- or decapeptide.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Examiner's amendments to the claims are as follows,

1. A process of removing residual organic solvent from ~~purification of~~ an otherwise pure nona- or decapeptide ~~from residual organic solvent~~, comprising the following steps:
 - dissolving the nona- or decapeptide in a dissolution solvent mixture comprising water and at least one alcohol selected from a group consisting of methanol, ethanol, propanol, isopropanol;
 - adding the solution of the nona- or decapeptide in said solvent mixture to a vigorously stirred precipitation solvent mixture ~~essentially~~ consisting essentially of one or several polar compounds selected from a group consisting of methyl acetate, ethyl acetate, methyl propionate, ethyl propionate, butyl acetate, isobutyl acetate, t-butyl acetate, ethyl formate, propyl formate and isopropyl formate, and one or several non-polar compounds selected from a group consisting of hexane, heptane, octane, cyclohexane and methylcyclohexane, and, optionally of up to 5% of acetic or propionic acid;
 - isolating the precipitated nona- or decapeptide;
 - washing the isolated nona- or decapeptide with one or a mixture of said polar compounds or a solvent or solvent mixture ^{of} ~~similar~~ polarity,
 - drying the washed nona- or decapeptide,

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with the proviso that the water content of said solvent mixture comprising water and at least one alcohol is below 8% (v/v), and that the volume ratio of the dissolution solvent mixture and the precipitation solvent mixture is 1:10 or more.

6. The process of claim 1, wherein the volume ratio of the dissolution solvent mixture and the precipitation solvent mixture is at least ~~15~~ 1:15.

10. (Canceled) The monoacetate of Ac-D-2Nal-D-4ClPhe-D-3Pal-Ser-MeTyr-D-Asn-Leu Lys(iPr)-Pro-D-Ala-NH₂.

Examiner's amendments to the specification are as follows,

Page 4, lines 5-8 of specification reads as follows,

5 According to a second preferred aspect of the invention the volume ratio of the dissolution solvent mixture and the Precipitation solvent mixture is at least ~~15~~ 1:15, in particular at least ~~20~~ 1:20.

Conclusion

Claims 1-9 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Satyanarayana R. Gudibande, Ph.D.
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A handwritten signature in black ink that reads "Bruce Campell". The signature is written in a cursive, flowing style.

**BRUCE R. CAMPPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**